Claims 5 and 32 find full support in the specification at page 11 lines 26-27. Accordingly, the claims are believed to be sufficiently definite and reconsideration of the rejections leading to their withdrawal and allowance of the claims is requested.

Claims 2-5, 12, and 32-35 are rejected under 35 U.S.C. 112, second paragraph as being vague and indefinite due to the lack of clarity of the mode of calculation which is meant by the asterix in all the formulations within the claims. Claims 2-5, 12, and 32- 35 have been amended to replace the asterix by parenthesis, to indicate multiplication. Parentheses are mathematical elements that are used by those of skill in the art to indicate multiplication. It is submitted that the claims are sufficiently definite and accordingly, reconsideration of the rejection in light of the amendments leading to withdrawal of the rejection and allowance of the claims is respectfully requested.

Claims 1-10, 12, and 32-37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the rejection proffers that "due to the lack of one of the two key hormones, glucagon, the extrapolated glucose concentration (G_p) is not enabled." See, pages 2-3 Paper No. 7. That proffer is respectfully traversed.

It is submitted that the rejection fails to meet the first element of prima facie nonenablement. Specifically, the rejection fails to set forth a reasonable basis that the specification is not enabling. Contrary to the proffer of the rejection, it is not necessary to include glucagon in the claimed method of the present invention.

The state of the art existing at the filing date of the application must be used to determine whether a particular disclosure is enabling as of the filing date. The Examiner has cited a biochemistry text, which states the importance of the hormone glucagon. It is acknowledged that glucagon is a hormone that counteracts many of the effects of insulin and increases blood glucose levels. There is no description or suggestion in said article, however, that requires that said hormone must be considered in all predictive methods.

In fact, as evidence of the state of the art at the filing date, the Examiner's attention is directed to U.S. Patent No.6,180,416 to Kurnik, which was filed on September 30, 1998. Kurnik discloses methods for measuring the concentration of target analytes using measurements and an algorithm. The Examiner's attention is

directed specifically to Example 1, beginning at Column 15, line 61. That example describes the use of an algorithm to predict blood glucose data. It is noted that glucagon was not considered in algorithm of Kurnik.

Therefore, given the state of the art at the time the invention was made it cannot be said that Applicants' disclosure is not enabled due the lack of glucagon. It is simply not necessary to include glucagon in the method of claim 1. Claims 2-10, 12, and 32-37 depend from claim 1. Accordingly, reconsideration of the rejection, leading to its withdrawal and allowance of the claims is respectfully requested.

Claims 2-5, 12, 32, 34, and 35 are rejected under 35 U.S.C. 112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The rejection proffers that given the lack of working examples in the specification, and the unpredictability of the selection of a functional value for the evaluation elements listed, the specification as filed is not enabling for the method of determining useful values for the evaluation elements as claimed.

The rejection is respectfully traversed. It is submitted that the rejection fails to meet the fifth element of prima facie nonenablement as it relates to each of the listed elements. Specifically, the rejection fails to demonstrate that the claimed invention requires undue experimentation since multiple dominant factors related to the showing of undue experimentation have not been met. Such elements will be addressed separately below:

1. Non-limiting examples of dominant factors demonstrating enablement of the claimed factor "D" of the claimed method include the fact that direction and guidance is presented in the application, determination of the factor's value would not require extensive experimentation, and that determination of this factor is rather predictable.

First, direction and guidance as to determination of a value for the factor D is found in the specification, beginning at page 11 line 1. Specifically, Applicants teach that the empirical weighting factor D, according to experiments, is between 0.05 and 0.5 mmol/./g. See, Col. 11 lines 4-5. In addition, the specification recites that the factor D is used to compensate for the proportionality between the actual glucose concentration (Ga) at the time of measurement and the patient's insulin sensitivity.

Thus, it is submitted that sufficient guidance and direction as to the determination of a value for the factor D is provided to one skilled in the art.

Second, based on this disclosed proportionality and the ability to determine a patient's individual glucose sensitivity, it is submitted that the determination of this factor D is rather predictable. In fact, the teaching of "proportionality" leads directly to the predictability of the value of the factor D. Accordingly, the only experimentation necessary to determine the value D would be to determine the patient's insulin sensitivity (as will be discussed below) and then to calculate the factor D, based on the glucose concentration measurements from the patient. Moreover, the disclosed experimental results further lead one of skill in the art to a desired value.

The fact that experimentation may be complex does not necessarily make it undue if a person skilled in the art typically engages in such experimentation. Here, it is submitted that those skilled in the art are more than capable of determining values for glucose concentration and insulin sensitivity and can conduct proportionality calculations. Accordingly, the factor D is believed to be enabled in accordance with 35 USC 112, first paragraph.

2. Non-limiting examples of dominant factors demonstrating enablement of the term "sensitivity" of the claimed method include the existence of a working example, that direction and guidance is presented in the application, the state of the prior art, determination of the factor's value would not require extensive experimentation, and that determination of this factor is rather predictable.

Although the rejection isolates the term "sensitivity", it is important to note that the term "sensitivity" is not claimed in isolation, but rather as part of the known phrase "insulin sensitivity". The Examiner's attention first is directed to Fig. 5 and page 15 line15 to page 16 line 6 where a working example utilizing insulin sensitivity is presented. The example shows insulin doses calculated and administered based on calculations using formula 9 ($ID = ((G_P - G_R)/SE*E) + Y$) while taking into account an insulin effectiveness kinetic according to Fig. 2 and a glucose flooding rate according to Fig. 3, wherein SE is insulin "sensitivity".

Guidance as to the determination of a patient's insulin sensitivity is further found at page 11 lines 5-13. Insulin sensitivity is defined in the specification as "the quantity of carbohydrate units that can be compensated by one unit of insulin". The specification is not required to teach every detail of the invention or to be a

production specification. It need only explain how to make and use the invention without requiring an inordinate amount of experimentation.

Further, it is submitted that the state of the art at the time the application was filed is such that one of ordinary skill in the art is aware how to determine a value of "insulin sensitivity". See, for example Column 8, lines 2-8 of U.S. Patent No. 5,822,715, ("the '715 Patent") which issued on October 13, 1998. The '715 Patent teaches that insulin sensitivity is calculated by "subtracting the pre-breakfast blood glucose value from the bedtime blood glucose value. The result is divided by the total number of units of insulin which had remaining insulin action at bedtime.". See, Col. 16 lines 24-28 of the '715 Patent. Thus, it is submitted that the term "sensitivity" is not subjective, but is part of a standard term, known in the art at the time the application was filed.

Based on the understood meaning of "insulin sensitivity", undue experimentation would not be necessary to determine its value. In fact, the art discloses known methods for determining its value and recognizes that a patient's insulin sensitivity is updated over time. See, Col. 16 lines 42-44 of the '715 Patent. The test of enablement is not whether experimentation is necessary, but if experimentation is undue. Here, the experimentation necessary to determine a value of insulin sensitivity is straightforward, predictable, and was known in the art at the time the application was filed. Accordingly, the term "insulin sensitivity" SE is believed to be enabled in accordance with 35 USC 112, first paragraph.

3. Non-limiting examples of dominant factors demonstrating enablement of the claimed "empirical weighting factor E" include the presence of a working example, that direction and guidance is presented in the application, determination of the factor's value would not require extensive experimentation, and that determination of this factor is rather predictable.

The Examiner's attention is again directed to figure 5 and page 15 beginning at line 15 where a working example using the factor "E" is presented. Moreover, guidance as to the determination of the factor "E" is also found at page 11 lines 14-19. Specifically, the specification teaches that the factor "E" is favorably $R_{KH}(F)$, whose terms are enabled as discussed below in sections 5 and 6. The specification is not required to teach every detail of the invention or to be a production specification. It need only explain how to make and use the invention without requiring an inordinate amount of experimentation.

Based on the working example as well as the guidance in the form a specific equation set forth in the specification, it is submitted that undue experimentation would not be necessary to determine a value of E. The test of enablement is not whether experimentation is necessary, but if experimentation is undue. Here, the experimentation necessary to determine a value of insulin sensitivity is straightforward, predictable, and was known in the art at the time the application was filed. Accordingly, the term "insulin sensitivity" SE is believed to be enabled in accordance with 35 USC 112, first paragraph.

4. Non-limiting examples of dominant factors demonstrating enablement of X being unequal to zero of the claimed method include the fact that direction and guidance is presented in the application, determination of the factor's value would not require extensive experimentation, and that determination of the factor is predictable.

First, direction and guidance as to determination of a value for the factor X is found in the specification, beginning at page 11 in the third paragraph. Specifically, the application teaches that the additive variable X is used to take into account the fact that blood glucose is increased by basal insulin demand during the projection period. X can be determined on empirical studies; by use of the equation $G_{basal} = I_{basal}$ (SE)(C) and or in the alternative, the variable X can contain the variable SG (A) as the addend. Thus, it is submitted that sufficient guidance and direction as to the determination of a value for the factor X is provided to one skilled in the art.

Second, based on this guidance and the ability of one skilled in the art to determine the basal insulin demand of a patent, it is submitted that the determination of this factor X is rather predictable. Accordingly, if one were to use the equation, the only experimentation necessary to determine the value X would be to determine the patient's insulin sensitivity (as previously discussed), the basal insulin demand, and to use the empirical weighting factor C (as will be discussed below). If the Examiner finds that this experimentation would be complex, it is noted that the fact that experimentation may be complex does not necessarily make it undue if a person skilled in the art typically engages in such experimentation. Here, it is submitted that those skilled in the art are more than capable of determining values for basal insulin demand, insulin sensitivity, and can conduct proportionality calculations. Accordingly, the factor X "is unequal to zero" is believed to be enabled in accordance with 35 USC 112, first paragraph.

5. Non-limiting examples of dominant factors demonstrating enablement of "R_{KH}" of the claimed method include a working example, that direction and guidance is presented in the application, determination of the factor's value would not require extensive experimentation, and that determination of this factor is rather predictable.

The Examiner's attention is again directed to figure 5 and page 15 beginning at line 15 where a working example using the factor "E" is presented, where E is defined as $R_{KH}(F)$. In addition, guidance as to the determination of the factor "R_{KH}" is found at page 11 lines 14-19. Specifically, R_{KH} is defined in the specification as a carbohydrate reduction factor that is used to reduce the effect of carbohydrates on blood glucose concentration. The specification is not required to teach every detail of the invention or to be a production specification. It need only explain how to make and use the invention without requiring an inordinate amount of experimentation.

Based upon the working example and the guidance provided in the specification, it is submitted that undue experimentation would not be necessary to determine a value for the term R_{KH}. The test of enablement is not whether experimentation is necessary, but if experimentation is undue. Here, the experimentation necessary to determine a value of a carbohydrate reduction factor is straightforward and predictable. Accordingly, the term R_{KH} is believed to be enabled in accordance with 35 USC 112, first paragraph.

6. Non-limiting examples of dominant factors demonstrating enablement of "F" of the claimed method include a working example, that direction and guidance is presented in the application, determination of the factor's value would not require extensive experimentation, and that determination of this factor is rather predictable.

The Examiner's attention is again directed to figure 5 and page 15 beginning at line 15 where a working example using the factor "E" is presented, where E is defined as $R_{KH}(F)$. In addition, guidance as to the determination of the factor "F" is found at page 11 lines 14-19. Specifically, F is defined in the specification as "a factor close to 0.25 mmol/l/g.

Based upon the working example and the guidance provided in the specification, namely that its value is close to 0.25 mmol/l/g, it is submitted that undue experimentation would not be necessary to determine a value for the term F. Accordingly, the term F is believed to be enabled in accordance with 35 USC 112, first paragraph.

7. Non-limiting examples of dominant factors demonstrating enablement of the term "GB" of the claimed method include a working example, that direction and guidance is presented in the application, determination of its value would not require extensive experimentation, and that determination of GB is predictable.

The rejection proffers that the quantity GB is not enabled due to the lack of enablement of SE (insulin sensitivity) and C (empirical weighting factor). The Examiner's attention is directed to paragraph 2 above and paragraph 8 below respectively. It is submitted that both SE and C are enabled in accordance with 35 USC 112, first paragraph. Accordingly, it is submitted that the term GB is enabled as well.

8. Non-limiting examples of dominant factors demonstrating enablement of the empirical weighting factor "C" of the claimed method include that direction and guidance is presented in the application, determination of the factor's value would not require extensive experimentation, and that determination of this factor is rather predictable.

First, direction and guidance as to determination of a value for the empirical weighting factor C is found in the specification, beginning at page 11 lines 23-25. Specifically, the application teaches that the factor C takes into account the proportionality of the increase in glucose concentration during the projection period to insulin sensitivity. Further, the specification states that C is preferably between 0.05 to 0.5 mmol/l/g. Thus, it is submitted that sufficient guidance and direction as to the determination of a value for the factor C is provided to one skilled in the art.

Second, based on this disclosed proportionality as well as a preferred range, it is submitted that the determination of this factor C is rather predictable. In fact, its stated preferred range provides further guidance. Accordingly, the weighting factor C is believed to be enabled in accordance with 35 USC 112, first paragraph.

9. Non-limiting examples of dominant factors demonstrating enablement of the term "SG" of the claimed method include that direction and guidance is presented in the application, determination of the its value would not require extensive experimentation, and that determination of its value is predictable.

The rejection proffers that the quantity SG is not enabled due to the lack of enablement of A (empirical weighting factor). The Examiner's attention is directed to paragraph 9 below. Further guidance is provided in the specification at page 11 lines

26 to page 12 line 2. It is submitted that A enabled in accordance with 35 USC 112, first paragraph. Accordingly, it is submitted that the term SG is enabled as well.

10. Non-limiting examples of dominant factors demonstrating enablement of the empirical weighting factor "A" of the claimed method include that direction and guidance is presented in the application, determination of the factor's value would not require extensive experimentation, and that determination of this factor is rather predictable.

Direction and guidance as to determination of a value for the empirical weighting factor A is found in the specification, at page 11 lines 26 to page 12 line 3. Specifically, the specification teaches that the factor A is preferably between 0 and 100 minutes. The test of enablement is not whether experimentation is necessary, but if experimentation is undue. Here, the experimentation necessary to determine a value A is straightforward and predictable, especially based upon the guidance provided by the specification. Thus, it is submitted that sufficient guidance and direction as to the determination of a value for the factor A is provided to one skilled in the art. Accordingly, the weighting factor A is believed to be enabled in accordance with 35 USC 112, first paragraph.

11. Non-limiting examples of dominant factors demonstrating enablement of the value of *m* of the summation of the claimed method include that direction and guidance is presented in the application, determination of the value would not require extensive experimentation, and that determination of this value is rather predictable.

Direction and guidance as to determination of a value for *m* is set forth at page 8 lines 16- 19 of the specification, where it is stated that "The integration indicated in formula (4) stands for all types of determination that . . . determine a portion of the carbohydrates that will become effective in the projection period by integrating a carbohydrate effectiveness profile, as in formula (1)." Consequently, KHj is a factor that takes into account the consumption of carbohydrates via carbohydrate consumption, j, and "m" indicates the number of carbohydrate consumption.

Determination of the value *m* would not require extensive experimentation but is determined by the carbohydrate consumption, and that determination of this value is easily determined. Thus, it is submitted that sufficient guidance and direction as to the determination of a value for *m* is provided to one skilled in the art. Accordingly, *m* is believed to be enabled in accordance with 35 U.S.C. 112, first paragraph.

Therefore, reconsideration of the rejections, leading to withdrawal of the rejection and allowance of claims 2-5, 12, 32, 34, and 35 is respectfully requested.

Claims 1-10, 12, and 32-37 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for how each of these evaluation elements functions separately. The rejection is respectfully traversed. It is submitted that the specification gives independent individual examples of each step of the extrapolation method of the claimed invention.

The extrapolation of claim 1 requires three steps:

a. determination of the portion (I_{wirk}) of insulin doses that take effect within the interval between t_a and t_p;

b. determination of the portion (KH_{wirk}) of carbohydrates consumed that take effect in the interval between t_a and t_p; and

c. determination of an extrapolated glucose concentration G_p at the point in time tp with consideration for I_{wirk} and KH_{wirk}.

Regarding step (a) of the claimed extrapolation, it is submitted that the specification gives examples of calculation formulas (1) and (3) for determining the portion of insulin doses that take effect within the interval between t_a and t_p. Neither of these formulas requires the consideration of carbohydrate information.

Regarding step (b) of the claimed extrapolation, it is submitted that the specification gives examples of calculation formulas (4) and (6) for determining the quantity of carbohydrates that is effective over the projection period. Neither of these formulas requires the consideration of the insulin doses.

Step (c) of the claimed extrapolation ties together steps (a) and (b) to determine an extrapolated glucose concentration. The specification supports greater than one alternative for the determination of the components that make up the necessary elements to extrapolate the glucose concentration. Thus, it is submitted that the specification enables greater than one set of elements to be evaluated in the glucose extrapolation. Thus, it is submitted that claim need not be limited as proffered by the rejection.

Claim 1 is believed to be enabled for purposes of 35 USC 112, first paragraph. Claims 2-10, 12, and 32-37 depend from claim 1. Accordingly, reconsideration of the rejection leading to its withdrawal and allowance of the claims is requested.

The claims are believed to be in condition for allowance, and allowance of the application is respectfully requested. It is requested that this paper be considered a

Petition for Extension of time sufficient to effect a timely response, and that all fees due be charged to Deposit Account Number 50-0877 with reference to (RDID 0006 US).

Respectfully submitted,
The Law Office of Jill L. Woodburn, L.L.C.

March 13, 2002
(Date)

Jill L. Woodburn
Registration No. 39,874

Clean Version of Replacement Claims for Entry During Prosecution of U.S. Application No. 09/711,855

1. System for the extrapolation of a glucose concentration, comprising:

a data input device for entering insulin doses administered (I_i) and their times of administration (t_i),

the same or a second data input device for entering carbohydrates (KH_j) consumed or to be consumed, and their times of consumption (t_j),

a unit for determining the actual glucose concentration (G_a) in a patient's bodily fluid at a specific point in time (t_a),

a memory unit for storing administered insulin doses and their times of administration, and carbohydrates consumed and their times of consumption,

an evaluation device for evaluating the data stored in the memory unit and extrapolating a glucose concentration at a point in time (t_p), whereby t_p is after t_a, and the extrapolation comprises the following steps:

determination of the portion (I_{wirk}) of insulin doses that take effect within the interval between t_a and t_p,

determination of the portion (KH_{wirk}) of carbohydrates consumed that take effect in the interval between t_a and t_p,

determination of an extrapolated glucose concentration G_p at the point in time tp with consideration for I_{wirk} and KH_{wirk}.

C1

2. (Amended) System according to Claim 1, in which the glucose concentration G_p is determined at the point in time using the following formula:

$G_p = G_a - I_{wirk}(D)(SE) + KH_{wirk}(E) + X$,

Sub E1

whereby D is an empirical weighting factor, SE is the patient's insulin sensitivity, E is a factor, and X=0 or is unequal to zero.

3. (Amended) System according to Claim 2, in which $E = R_{KH}(F)$, whereby R_{KH} is the carbohydrate reduction factor and F is an empirical factor.

4. (Amended) System according to Claim 2, in which X, as the addend is equal to GB, whereby $GB = I_{basal}(SE)(C)$ and I_{basal} is the patient's basal insulin demand over 24 hours, SE is the patient's insulin sensitivity, and C is an empirical weighting factor.

C2 Sub D2

5. (Amended) System according to Claim 2, in which X, as the addend, contains the quantity SG(A), whereby SG is the slope of the glucose concentration at the point in time t_a, and A is an empirical weighting factor.

6. System according to Claim 1, in which the unit used to determine the actual glucose concentration G_a is a microdialysis device.

7. System according to Claim 1 that also includes a display unit for displaying the extrapolated glucose concentration G_p.

8. System according to Claim 1 that also includes a warning unit that emits a warning signal when the extrapolated glucose concentration G_P is outside a selected normal range.

9. System according to Claim 1 in which the user enters the carbohydrate units consumed (KH_j).

10. System according to Claim 1 in which the system contains a control unit for an insulin infusion device or is connected to such a device, and in which the insulin doses administered (I_i) and their times of administration (t_i) are transmitted from the control unit to the date input device for entering insulin doses.

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12. (Amended) System according to Claim 1 in which the quantity of carbohydrates consumed (KH_{wirk}) that takes effect in the period between t_a and t_p is calculated using the following formula

$$KH_{WIRK} = \sum_{j=1}^{m} \int_{t_a}^{t_p} C_{KH}(t)dt\,(KH_j)$$

whereby C_{KH} represents the quantity of carbohydrates that are bioavailable at the point in time t and therefore represents the carbohydrate flooding profile, with

$$\int_0^{\infty} C_{KH}(t)dt = 1.$$

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32. (Amended) System according to Claim 4, in which X, as the addend, contains the quantity SG (A), whereby SG is the slope of the glucose concentration at the point in time ta, and A is an empirical weighting factor.

33. (Amended) System according to claim 1 in which the portion of insulin doses (I_{wirk}) that take effect in the period between t_a and t_p is calculated using the following formula

$$I_{WIRK} = \sum_{i=1}^{n} \int_{t_a}^{t_p} C_I(t)dt\,(I_i);\ n = \text{number of insulin doses to be considered}$$

whereby CI represents the quantity of insulin that is bioavailable at the point in time t and therefore represents the insulin effectiveness profile; with

$$\int_0^\infty C_I(t)dt = 1.$$

34. (Amended) System according to claim 2 in which the portion of insulin doses (I_{wirk}) that take effect in the period between t_a and t_p is calculated using the following formula

$$I_{WIRK} = \sum_{i=1}^{n} \int_{t_a}^{t_p} C_I(t)dt\,(I_i);\ n = \text{number of insulin doses to be considered}$$

whereby CI represents the quantity of insulin that is bioavailable at the point in time t and therefore represents the insulin effectiveness profile; with

$$\int_0^\infty C_I(t)dt = 1.$$

35. (Amended) System according to Claim 2 in which the quantity of carbohydrates consumed (KH_{wirk}) that takes effect in the period between t_a and t_p is calculated using the following formula

$$KH_{WIRK} = \sum_{j=1}^{m} \int_{t_a}^{t_p} C_{KH}(t)dt(KH_j)$$

whereby C_{KH} represents the quantity of carbohydrates that are bioavailable at the point in time t and therefore represents the carbohydrate flooding profile, with

$$\int_0^\infty C_{KH}(t)dt = 1.$$

36. System according to Claim 1, in which the point in time t_p is from 0.5 to 5 hours after t_a.

37. System according to Claim 1, in which the point in time t_p is at least 2 hours after t_a and up to 4 hours after t_a.

Version with Markings to Show Changes Made

2. (Amended) System according to Claim 1, in which the glucose concentration G_p is determined at the point in time using the following formula:

[$G_p = G_a - I_{wirk} * D * SE + KH_{wirk} * E + X$] $\underline{G_p = G_a - I_{wirk}(D)(SE) + KH_{wirk}(E) + X}$,

whereby D is an empirical weighting factor, SE is the patient's insulin sensitivity, E is a factor, and X=0 or is unequal to zero.

3. (Amended) System according to Claim 2, in which [$E = R_{KH} * F$] $\underline{E = R_{KH}(F)}$, whereby R_{KH} is the carbohydrate reduction factor and F is an empirical factor.

4. (Amended) System according to Claim 2, in which X, as the addend[, contains the quantity $GB = I_{basal} * SE * C$ or] is equal to GB, whereby $\underline{GB = I_{basal}(SE)(C)}$ and I_{basal} is the patient's basal insulin demand over 24 hours, SE is the patient's insulin sensitivity, and C is an empirical weighting factor.

5. (Twice Amended) System according to Claim 2, in which X, as the addend, contains the quantity [SG * A] $\underline{SG(A)}$, whereby SG is the slope of the glucose concentration at the point in time t_a, and A is an empirical weighting factor.

12. (Amended) System according to Claim 1 in which the quantity of carbohydrates consumed (KH_{wirk}) that takes effect in the period between t_a and t_p is calculated using the following formula

$$[KH_{WIRK} = \sum_{j=1}^{m} \int_{t_a}^{t_p} C_{KH}(t)dt * KH_j]$$

$$\underline{KH_{WIRK} = \sum_{j=1}^{m} \int_{t_a}^{t_p} C_{KH}(t)dt\,(KH_j)}$$

whereby C_{KH} represents the quantity of carbohydrates that are bioavailable at the point in time t and therefore represents the carbohydrate flooding profile, with

$$\int_0^{\infty} C_{KH}(t)dt = 1.$$

32. (Amended) System according to Claim 4, in which X, as the addend, contains the quantity [SG * A] $\underline{SG(A)}$, whereby SG is the slope of the glucose concentration at the point in time ta, and A is an empirical weighting factor.

33. (Amended) System according to claim 1 in which the portion of insulin doses (I_{wirk}) that take effect in the period between t_a and t_p is calculated using the following formula

$$[I_{WIRK} = \sum_{i=1}^{n} \int_{t_a}^{t_p} C_I(t)dt * I_i;\ n = \text{number of insulin doses to be considered}]$$

$$\underline{I_{WIRK} = \sum_{i=1}^{n} \int_{t_a}^{t_p} C_I(t)dt\ (I_i);\ n = \text{number of insulin doses to be considered}}$$

whereby CI represents the quantity of insulin that is bioavailable at the point in time t and therefore represents the insulin effectiveness profile; with

$$\int_0^{\infty} C_I(t)dt = 1.$$

34. (Amended) System according to claim 2 in which the portion of insulin doses (I_{wirk}) that take effect in the period between t_a and t_p is calculated using the following formula

$$[I_{WIRK} = \sum_{i=1}^{n} \int_{t_a}^{t_p} C_I(t)dt * I_i;\ n = \text{number of insulin doses to be considered}]$$

$$\underline{I_{WIRK} = \sum_{i=1}^{n} \int_{t_a}^{t_p} C_I(t)dt\ (I_i);\ n = \text{number of insulin doses to be considered}}$$

whereby CI represents the quantity of insulin that is bioavailable at the point in time t and therefore represents the insulin effectiveness profile; with

$$\int_0^{\infty} C_I(t)dt = 1.$$

35. (Amended) System according to Claim 2 in which the quantity of carbohydrates consumed (KH_{wirk}) that takes effect in the period between t_a and t_p is calculated using the following formula

$$[KH_{WIRK} = \sum_{j=1}^{m} \int_{t_a}^{t_p} C_{KH}(t)dt * KH_j]$$

$$\underline{KH_{WIRK} = \sum_{j=1}^{m} \int_{t_a}^{t_p} C_{KH}(t)dt(KH_j)}$$

whereby C_{KH} represents the quantity of carbohydrates that are bioavailable at the point in time t and therefore represents the carbohydrate flooding profile, with

$$\int_0^{\infty} C_{KH}(t)dt = 1.$$